

Office of Drug Enforcement and Program Compliance
49 CFR Part 40 Interpretation

Question: When a urine specimen is outside the required temperature range and the donor declines to supply an additional specimen under observation, should the result of the specimen be reported as negative or canceled if it returns from the laboratory as being negative?

Response: Section 40.25 states: *"... the following circumstances are ... grounds constituting a reason to believe that the individual may alter or substitute the specimen: ... the employee has presented a urine specimen that falls outside the normal temperature range and ... the employee declines to provide a measurement of oral body temperature or ... oral body temperature varies by more than 1 degree C / 1.8 degrees F."* Section 40.25 goes on to state: *"Whenever there is a reason to believe that a particular individual has altered or substituted the specimen ... a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person."*

The collection site person, using the appropriate collection protocol, is required to obtain another specimen under direct observation. Failure of the individual to submit to this direct observation collection constitutes a refusal to be tested and is a violation of DOT rules. The collection site person shall report the employee's refusal to the employer for appropriate action.

Action on the part of the employer is required under a governing DOT regulation. For instance, the Federal Highway Administration rule, 382.211, states, *"No driver shall refuse to submit to a ... controlled substance test."* And, *"No employer shall permit a driver who refuses to submit to such tests to perform or continue to perform safety-sensitive functions."*

While the MRO should report the laboratory negative result as negative, it is the MRO's responsibility to ensure that safety is served in such matters. Therefore, it is appropriate for the MRO to reconstruct for the employer the events of the collection, ensure that the employer is aware of the violation, and appraise the employer of appropriate action to be taken. The negative test result on the first specimen would not override a refusal to provide a specimen under direct observation.